



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,279	12/11/2001	Johnny Paul Speir	140-067a	2332

7590 04/25/2005
Ward & Olivo
708 Third Ave
New York, NY 10017

EXAMINER

LIN, JERRY

ART UNIT PAPER NUMBER

1631

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/014,279

Applicant(s)

SPEIR, JOHNNY PAUL

Examiner

Jerry Lin

Art Unit

1631

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 20 December 2004. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see continuation sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.

Claims 15, 18, 21, 24, and 27 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Applicant has responded to this rejection by stating that the specification states that the present invention provides "a means for the rapid screening of drug dosed, biological samples." However even this statement makes no mentions of injecting drugs into biological samples. Drug-dosing and injecting drugs are not inherently the same and they do not have the same limitations. Therefore the above limitation constitutes new matter that was not previously disclosed as part of the methods currently claimed.

Claims 1-11 and 15-26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yates (Journal of Mass Spectrometry, January 1998, Vol.33, pp. 1-19) in view of Dasseux et al. (US 2002/0019023 A1).

Applicants have responded to this rejection by stating that Yates does not teach a method for characterizing each species nor does Yates teach using molecular weight to determine the empirical formula of each species. The Examiner disagrees. Yates states "Each of the fragment ions represents part of the amino acid sequence, and consequently the pattern as a whole forms a unique signature much the same way that a mass map can be a unique fingerprint for a protein sequence. The third level of information present in a tandem mass spectrum is the actual sequence." (page 9, column 2). Furthermore, Yates states, "Successful interpretation involves determining which ions originate from the *N*- or *C*-terminus so mass differences between consecutive ions of the same type can be calculated. Hence a set of sequence ions, from low mass to high mass, will define the amino acid sequence." (page 10, column 2). From these statements, Yates does teach using molecular weight to determine the empirical formula of each species.

In addition, Yates does teach a method of characterizing each species. Yates discusses a variety of methods peptides may be delivered to a mass spectrometer (page 5, column 2 - page 7, column 1). Once the peptides are delivered to mass spectrometer, mass analysis may commence on each of the species. Furthermore, it is noted that the claims as written do not require that more than one species is found in a sample. It is within the scope of the claims that only one species is characterized and analyzed in a sample.

Applicants have responded to the Dasseux et al. reference by stating that Dasseux et al. do not teach using molecular weight to determine the empirical formula of each species present in said sample, nor identifying each said species. The Applicant's response does not apply to the prior art the Examiner cited from Dasseux et al. The Examiner did not rely upon Dasseux et al. for a method of using molecular weight to determine the empirical formula. Instead, Yates was relied upon to show this method. Thus Dasseux et al. still applied as in the previous office action.

Applicants have also responded to this rejection by stating that Dasseux et al. teaches away from the invention. The applicant cite a passage that state the peaks "are not identifiable, at least initially, until databases of HICS-FTMS peak profiles and the identifies of molecules corresponding to those individual peaks are compiled" (paragraph 0131 of Dasseux). However the passage does not state that it is impossible to identify the peaks or that the peaks are unidentifiable, rather Dasseux et al. is merely saying that the databases must be compiled before identification. This condition does not teach away from the combination of Yates with Dasseux et al.

Claims 12-14 and 27-29 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yates in view of Franzen et al. (US 5663561), further in view of Dasseux et al. (US 2002/0019023 A1).

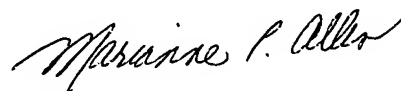
Applicants have responded to this rejection by stating that Franzen does not disclose any techniques for compound identification of empirical formula determination and that Franzen only teaches a method of ionizing large, non-polar molecules at atmospheric pressure. First, Franzen was not relied upon to teach a method of compound identification of empirical formula. Yates was relied upon to show a teaching of this method as was discussed above. Second, Franzen et al. uses atmospheric pressure chemical ionization (column 2, lines 45-46), and also employs a method of positive or negative chemical ionization (column 2, line 50) with the atmospheric pressure chemical ionization. Thus Yates, Franzen and Dasseux does teach the instant limitations.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 6:30-3:00, M-F. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JL



MARIANNE P. ALLEN
PRIMARY EXAMINER

AU 1631

4/22/05